

EN

EN

EN



COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 10.7.2008

C(2008)3663

NOT FOR PUBLICATION

COMMISSION DECISION

of 10.7.2008

amending the marketing authorisation for "PegIntron - Peginterferon alfa-2b", a medicinal product for human use, granted by Decision C(2000)1407

(ONLY THE FRENCH, DUTCH TEXT IS AUTHENTIC)

COMMISSION DECISION

of 10.7.2008

amending the marketing authorisation for "PegIntron - Peginterferon alfa-2b", a medicinal product for human use, granted by Decision C(2000)1407

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency¹,

Having regard to Commission Regulation (EC) No 1085/2003 of 3 June 2003 concerning the examination of variations to the terms of a marketing authorisation falling within the scope of Council Regulation (EEC) No 2309/93², and in particular the third subparagraph of Article 4(5), and the first subparagraph of Article 6(10) thereof,

Having regard to the application submitted by Schering Plough Europe on 30 March 2008 under Article 6(1) of Commission Regulation (EC) No 1085/2003,

Having regard to the notification submitted by Schering Plough Europe under Article 4(1) of Regulation (EC) No 1085/2003,

Having regard to the opinion(s) of the European Medicines Agency, formulated by the Committee for Medicinal Products for Human Use on 30 May 2008,

Whereas:

- (1) An examination of the major variation(s) type II to the terms of the marketing authorisation for the medicinal product "PegIntron - Peginterferon alfa-2b", which is entered in the Community Register of Medicinal Products under number(s) EU/1/00/131/001-050 and the placing on the market of which was authorised by Decision C(2000)1407 of 25 May 2000, has shown that the product remains in compliance with the requirements set out in Directive 2001/83/EC of the

¹ OJ L 136, 30.4.2004, p. 1, Regulation as last amended by Regulation (EC) No 1394/2007 (OJ L 324, 10.12.2007, p. 121).

² OJ L 159, 27.6.2003, p. 24.

European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use³.

- (2) It is therefore appropriate to accept the application(s) in respect of (a) major variation(s) to the terms of the marketing authorisation and to amend Decision C(2000)1407 accordingly.
- (3) The European Medicines Agency acknowledged, between 21 May 2008 and 30 May 2008, the validity of the notification(s) for minor variations of type IA, informing the marketing authorisation holder accordingly, and has prepared a list of the notification(s). The variation(s) took effect from the date of the communication from the European Medicines Agency concerning the validation.
- (4) The marketing authorisation should be updated, and Decision C(2000)1407 amended accordingly.
- (5) For the sake of clarity and transparency, it is advisable, following the amendment of part or parts of the Annexes, to provide for a consolidated version thereof. The Annexes to Decision C(2000)1407 should therefore be replaced,

HAS ADOPTED THIS DECISION:

Article 1

Decision C(2000)1407 is amended as follows:

- 1) The following list of notifications for minor variations is added to the updated marketing authorisation.

Application number	Scope (EU numbers affected)
EMEA/H/C/280/IA/0081	8.b.1 (IA) (EU/1/00/131/001-050)

- 2) Annex I is replaced by the text set out in Annex I to this Decision;
- 3) Annex II is replaced by the text set out in Annex II to this Decision;
- 4) Annex III B is replaced by the text set out in Annex III B to this Decision.

³ OJ L 311, 28.11.2001, p. 67, Directive as last amended by Directive 2008/29/EC (OJ L 81, 20.3.2008, p.51).

Article 2

This Decision is addressed to Schering Plough Europe, Rue de Stalle, 73, 1180 Bruxelles, Belgique - Stallestraat, 73 - 1180 Brussel, België.

Done at Brussels, 10.7.2008

For the Commission
Heinz ZOUREK
Director-General